

FORM PTO-1449 (Modified)

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S  
INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

ATTY. DOCKET NO.  
02940086PASERIAL NO.  
09/944,221APPLICANT:  
J. Peart, et al.FILING DATE:  
September 4, 2001GROUP:  
1617

## REFERENCE DESIGNATION

## U.S. PATENT DOCUMENTS

EXAMINER INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPRO.)
JHNA	5,492,688	02/20/96	P. Byron, et al.			3/23/94
	5,736,124	4/7/98	R. Akehurst, et al.			05/30/95
	5,916,540	6/29/99	R. Akehurst, et al.			4/6/98
JHNA	5,922,306	7/13/99	R. Akehurst, et al.			4/15/98

## FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO

## OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

Not provided		T. Tzou. DENSITY, EXCESS MOLAR VOLUME, AND VAPOR PRESSURE OF PROPELLANT MIXTURES IN METERED-DOSE INHALERS: DEVIATION FROM IDEAL MIXTURES: T. Tzou: Respiratory Drug Delivery. VI, 1998 439-443
		J. H. Bell, et al.: Variation in delivery of isoprenaline from various pressurized inhalers. J. Pharm Pharmac. 1973, Suppl. 32P-36P
JHNA		F. Moren: Drug Deposition of pressurized inhalation aerosols Influence of vapour pressure and metered volume; Int'l Journal of Pharmaceuticals. 1 (1978) 213-218

EXAMINER

DATE CONSIDERED

12/17/05

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98-70

SERIAL NO.

09/944 221

APPLICANT:  
J. Peart, et al.

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9-4-01

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OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

JHAA	Long-Term Efficacy and Safety of Dronabinol for Acquired Immunodeficiency Syndrome-Associated Anorexia, Journal of Pain and Symptom Management; Vol. 14 No. 1 July 1997 pgs 7-14
	Dronabinol as a Treatment for Anorexia Associated with Weight Loss in Patients with AIDS; Journal of Pain and Symptom Management; Vol. 10 No. 2; February 1995; pgs 89-97
	Efficacy of tetrahydrocannabinol in patients refractory to standard antiemetic therapy; Investigational New Drugs 6:243-246; (1988); Mary McCabe, Frederick P. Smith, John S. Macdonald, Paul V. Woolley, Deborah Goldberg, and Philip S. Schien; Divisional of Medical Oncology, Vincent T. Lombardi Cancer Research Center, Dept. of Medicine, Georgetown University
	Tetrahydrocannabinol for Refractory Vomiting Induced by Cancer Chemotherapy; JAMA March 28, 1980-Vol 243, No. 12
	ANTIEMETICS-SALLAN, ET AL. The New England Journal of Medicine; Jan. 17, 1980; Vol 302 No. 3; pgs 135-138
	Delta-9-Tetrahydrocannabinol as an Antiemetic for Patients Receiving Cancer Chemotherapy; December 1979; Annals of Internal Medicine; Vol 91 No. 6; pgs. 825-830
	Delta-9-Tetrahydrocannabinol as an Antiemetic in Cancer Patients Receiving High-Dose Methotrexate; December 1979; Annals of Internal Medicine; Vol. 91 No. 6; pgs. 820-824
	Analgesic effect of Delta-9-tetrahydrocannabinol; Dept. of Psychiatry and Internal Medicine, University of Iowa College; Feb-March 1975; pgs. 139-143
	Analgesic Properties of delta-9-tetrahydrocannabinol and codeine; Depart., of Psychiatry and Medicine, University of Iowa; published March 29, 1975; pgs 84-89
	The effect of orally and rectally administered 9-tetrahydrocannabinol on spasticity: A pilot study with 2 patients; Institute of Pharmacy, University of Bern; International Journal of Clinical Pharmacology and Therapeutics, Vol 34 No. 10-1996 (446-452)
JHAA	Delta-9-THC in the Treatment of Spasticity Associated with Multiple Sclerosis; Dept. of Psychiatry at U.C.L.A.; 1988 Hawthorne Press; pgs. 39-50.
	Tetrahydrocannabinol for Tremor in Multiple Sclerosis, David Clifford, MD, Division of Clinical Neuropharmacology and Dept. of Neurology and Neurological Surgery Washington School of Medicine, Published December 12, 1982; Annals of Neurology Vol 13 No. 6 June 1983; pgs 669-671
	Treatment of Human Spasticity with 9-Tetrahydrocannabinol; J. Clin Pharmacol. 1981;21:413S-416S
	Delta-9-tetrahydrocannabinol shows antispastic and analgesic effects in a single case double blind trial; Eur Arch Psychiatry Clin Neurosci 1990;240(1):1-4
	Effect of Marijuana on Intraocular and Blood Pressure in Glaucoma; American Academy of Ophthalmology; March 1980 Vol. 87 Number 3; pgs. 222-228
	Effect of Delta-9-Tetrahydrocannabinol on Intraocular Pressure in Humans; August 1977; Southern Medical Journal Vol., 70 No. 8; pgs. 951-954
	ANTIEMETIC EFFECT OF Delta-9 Tetrahydrocannabinol in patients receiving Cancer Chemotherapy, New England Journal of Medicine; October 16, 1975, Vol. 293 No. 16 pgs. 795-797

Not provided or found in records of parent case

12/17/05

<i>JHAA</i>		Comparison of Ozone Size Distributions from Pressurized Aerosols Formulations or Suspensions; Pharmaceutical Research Vol. 5 No. 1, 1988, Plenum Publishing Corp. pgs. 36-39
<i>JHAA</i>		Changing to CFC-Free Inhalers: The Technical and Clinical challenges; The Pharmaceutical Journal Vol. 259; November 29, 1997; pgs 896-898
<i>JHAA</i>		Drug-surfactant-propellant interactions in HFA-formulations; International Journal of Pharmaceutics; 186 (1999) 13-30
<i>JHAA</i>		Drug form Selection in Albuterol-containing Metered-Dose Inhaler Formulations and its Impact on Chemical and Physical Stability; Journal of Pharmaceutics Sciences; Vol 86 No. 12, December 1997 pgs. 1352-1357
<i>JHAA</i>		The Identification, isolation, and preservation of 9-tetrahydrocannabinol Detp. Of Toxicology, Indiana University Med. Ctr., J. Pharm. 1971, 23, 190-195
<i>JHAA</i>		Stability of Tetrahydrocannabinols I J. Pharmaceutics Sciences Vol. 63, No. 10., October 1974; pgs. 1563-1574

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*12/17/05*

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**(Use several sheets if necessary)**

**' 02940086P,**

09/944,221

J. Peart et al.

9-4-01

**GROUP**

[illegible][illegible]

2/17/90		Ross, S., et al.; Constituents of Cannabis Sativa L. XXXVIII; A Review of the Natural Constituents: 1980-1994; Zagazig J Pharm Sci, December, 1995; Vol. 4, No. 2, pp. 1-10.
		Tashkin, DP, et al. Subacute Effects of Heavy Marihuana Smoking on Pulmonary Function in Healthy Men; New Eng. J of Med. 294:125-129, January 15, 1976.
		Turner, et al., Constituents of Cannabis sativa L. XVIII - Electron Voltage Selected Ion Monitoring Study of Cannabinoids; Biomedical Mass Spectrometry, Vol., 7, No. 6, 1990 pp. 247-256.
2/17/90		Maurer et al.; Delta9 tetrahydrocannabinol Shows Antispastic and Analgesic Effects in a Single Case Double-blind Trial; Eur Arch Psychiatry Clin Neurosci 240:1-4, 1990.

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-FORM PTO-1449 (Modified)  LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)	ATTY. DOCKET NO. 98-70	SERIAL NO. 09844221
	APPLICANT: J. Peart, et al.	
	FILING DATE: 9-4-01	GROUP:

# REFERENCE DESIGNATION

# U.S. PATENT DOCUMENTS

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# FOREIGN PATENT DOCUMENTS

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						YES	NO

# OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)

Not provided	Asgharian, B., Wood, r. & Schlesinger, R.B. (1995). Empirical modeling of particle deposition in the alveolar region of the lungs: A basis for interspecies extrapolation. Fund Appl toxicol, 27, 232-238.
	Barnett, C., Chiang, C., Perez-Reyes, M. & Owens, S. (1982). Kinetic study of smoking marijuana. J. Pharmacokin Biopharm, 10, 495-506
	Byron, P.R. (1994) Dosing reproducibility from experimental albuterol suspension metered-dose inhalers. Pharm Res, 11, 580-4.
	Chiang, C.W. & Barnett, G. (1984). Marijuana effect and delta-9-tetrahydrocannabinol plasma level. Clin Pharmacol Ther, 36-234-238.
	Christensen, H.d., Freudenthal, R.I., Gidley, J.T., Rosenfeld, R., Boegh, G., Testino, L., Brine, D.R., Pin, C.G., & Wall, M.E. (1971) Activity of Delta8-and Delta-9-tetrahydrocannabinol and related compounds in the mouse. Science, 172, 165-167
	Compton, D., Aceto, M., Lowe, J. & Martin, B. (1996) In vivo characterization of a specific cannabinoid receptor antagonist (SR141716A): inhibition of delta 9-tetrahydrocannabinol-induced responses and apparent agonist activity. J. Pharmacol Exp. Ther. 277,586-594.
	Compton, D.R., Rice, K.C., De Costa, B.R., Razdan, R.K., Melvin, L.S., Johnson, M.R. & Marin, B.R. (1993). Cannabinoid structure-activity relationships: Correlation of receptor binding and in vivo activities. J. Pharmacol Exp Ther, 265, 218-226.
	Cone, E. & Huestis, M., (1993). Relating blood concentrations of tetrahydrocannabinol and metabolites to pharmacologic effects and time of marihuana usage. Ther Drug Mon, 15, 527-532.
	D'Amour, F.E. & Smith, D.L. (1941) A method for determining loss of pain sensation. J. Pharm Exp Ther, 72, 74-79
	Ford, R.D., Balster, R.L., Dewey, W.L., & Beckner, J.S., (1977). Delta 9-THC and 11-OH-delta 9-THC: Behavioral effects and relationship to plasma and brain levels. Life Sci., 20, 1993-2000-4.
	Gill, E. W. & Jones, J. (1972) Brain levels of delta 1-tetrahydrocannabinol and its metabolites in mice-correlation with behavior, and the effect of the metabolic inhibitors SKF 525A and piperonyl butoxide. Biochem. Pharmacol., 21, 2237-2248.
	Gupta, P.K. & Hickey, A. J. (1991). Contemporay approaches in aerosolized drug delivery to the lungs. J. Controlled release, 17, 129-148.
	Henderson, R., Tennant, F., & Guernsey, R. (1972) Respiratory manifestations of hashish smoking. Arch Otol, 95, 248-251.
	Hiller, F.C., Wison, F.J.J., Mazumder, M.K., Wison, J.D. & Bone, R.C., (1984) Concentration and particle size distribution in smoke from marijuana cigarettes with different delta 9-tetrahydrocannabinol content. Fundam Appl Toxicol, 4,451-454.
	House-of-Lords-Select-Committee-on-Science-and-Technology (1998). Ninth Report. Cnnabis: The Scientific and Medical Evidence.
Not provided	Huber, G.L., Simmons, G.A., McCarthy, C.R., Cutting, MB., Laguarda, R. & Pereira, W. (1975) Depressant effect of marijuana smoke on antibactercidal activity of pulmonary alveolar macrophages. Chest, 68, 769-73.
	Huestis, M.A., Sampson, A.H., Holicky, B.J., Henningfield, J.E. & Cone, E.J. (1992) Characterization of the absorption phase of marijuana smoking. Clin Pharmacol Ther, 52, 31-41.
	Johnson, E., Ohlsson, A., Lindgren, J.E., Agurell, S., Gillespies, H. & Hollister, L. E. (1987) Single dose kinetics of deuterium-labelled cannabinal in man after intravenous admistration and smoking. Biomed Environ Mass Spectrum, 14, 495-499

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12/13/05

JHAA		Lichtman, A.H., Pearl, J.L., Bridgen, D.T., Razdan, R.K., Wilson, D.M., Poklis, Y., Byron, P.R. & Martin, B.R. (2000) Pharmacological evaluation of aerosolized cannabinoids in mice. Eur J. Pharmacol, 399, 11-149.
		Lichtman, A.H., Poklis, J.L., Poklis, A., Wilson, D.M. & Martin, B.R. (2001) The pharmacological activity of inhalation exposure to marijuana smoke in mice. Drug Alc Depend 63, 107-116.
		Little, P.J., Compton, D.r., Johnson, MR., Melvin, L.S. & Martin, B.R. (1988) Pharmacology and stereoselectivity of structurally novel cannabinoids in mice. J. Pharmacol Exp Ther, 247, 745-747.
		Mattes, R.D., Shaw, L.M., Edling-Owens, J., Engleman, K. & Elsohly, M.A. (1993) Bypassing the first-pass effect for the therapeutic use of cannabinoids. Pharmacol Biochem Behav, 44, 745-747
		Matthias, P., Tashkin, DP., Marques-Magallanes, J.A., Wilkins, J.N. & Simmons, M.S. (1997) Effects of Varying Marijuana Potency on Deposition of Tar and Delta 9-THC in the Lung During Smoking. Pharmacol Biochem Behav. 58, 1145-1150.
		Ohlsson, A., Lindgren, J.E., Wahleim, A., Agurell, S., Hollister, L. E. & Gillespie, H.K. (1980) Plasma delta-9 tetrahydrocannabinol concentrations and clinical effects after oral and intravenous administration and smoking. Clin Pharmacol Ther, 28, 409-16.
JHAA		Ohlsson, A., M. Widman, M., Carlsson, S., Ryman, I., & Strid, C. (1980) Plasma and brain levels of delta 6-THC and seven monooxygenated metabolites correlated to the cataleptic effect in the mouse. Acta Pharmacol. Et Toxicol., 47, 308-317
Not provided		Perlin, E., Smith, C.G., Nichols, A.I., Almirez, r., Flora, K.P., Craddock, J.C. & Peck, C.C. (1985) Disposition and bioavailability of various formulations of tetrahydrocannabinol in the rhesus monkey. J. Pharm Sci, 74, 171-174.
JHAA		rinaldi-Carmona, M., Barth, F., Heaulme, M., Shire, D., Calandra, B., Congy, C., Martinez, S., Maruani, J., Neliat, G., Caput, D., Ferrara, P., Soubrie, P., Breliere, J.C., & Lefur, G. (1994) SR141716A, a potent and selective antagonist of the brain cannabinoid receptor. GEBS Lett, 350, 240-244
JHAA		Schlesinger, R.B. (1985) Comparative deposition of inhaled aerosols in experimental animals and humans a review. J. Toxicol Environ Health, 15, 197-214
Not provided		USP (2000) Physical Tests and Determinations <601> Aerosols, metered-dose inhalers, and dry powder inhalers. In United States Pharmacopeia (USP 24) PP. 1895-1912. Philadelphia, PA: National Publishing
JHAA		Vachon, L., Robins, A. & Gaensler, E.A. (1976) Airways response to aerosolized delta 9-tetrahydrocannabinol: preliminary report. In The Therapeutic potential of marijuana. Ed. Cohem, S. & Stillman, R.C. pp 111-121. New York: Plenum Medical Book Company
Not provided		Vaswani, S.K. & Criticos, P.S. (1998) Metered dose inhaler: past, present, and future. Ann Allergy Asthma Immunol, 80, 11-9; quiz 19-20

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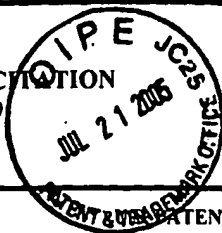
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# INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)



Docket Number (Optional) <b>02940086AA</b>	Application Number <b>10/759,280</b>
Applicant(s) <b>Peart et al.</b>	
Filing Date <b>1-20-04</b>	Group Art Unit <b>1616</b>

## U.S. PATENT DOCUMENTS

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## U.S. PATENT APPLICATION PUBLICATIONS

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							YES	NO
<i>JHAA</i>	1	WO 98/24420	6-11-98	PCT				✓

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

<i>JHAA</i>	1	XP008034315, Ungerleider et al. "Cannabis and Cancer Chemotherapy" A comparison of Oral-9-THC and Prochlorperazine; American Cancer Society ppg. 636-345, 1982,
<i>JHAA</i>	2	XP-000961105, Vanchon et al. "Airways to Micro-Aerosolized Delta-9 Tetrahydrocannabinol" 42 Annual Scientific Assembly; September 1976

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U.S. PATENT DOCUMENTS									
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JH	1	4,635,651	1-13-97	Jacobs			8-29-80		
JH	2	5,804,592	9-8-98	Volicer			5-30-97		
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							YES	NO	
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JH	1	XP008034296 J.L. Olsen et al. "An inhalation aerosol of $\Delta^9$ - tetrahydrocannabinol " June 19, 1975							
JH	2	XP000961016 Tashkin et al. "Bronchial Effects of Aerosolized $\Delta^9$ - Tetrahydrocannabinol in Healthy and Asthmatic Subjects" American review of respiratory disease, pp. 57-65, VOL. 155, 1977							
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